REMARKS

Reconsideration is requested. Claims 1-10 are pending. Responsive to the Office Action of May 21, 2002, the Examiner's comments and the cited art have been noted and studied. For reasons to be set forth in detail below, it is respectfully submitted that the present application is in condition for allowance, and such action is requested.

Applicant notes that the Examiner has required a new declaration or oath. Applicant has attached herewith a supplemental declaration in compliance with 37 CFR 1.67(a). Applicant has also noted the objections to the disclosure and has amended the disclosure accordingly.

Claim 1 has been amended to recite that "the second stop junction is weaker than the first stop junction such that the excess sample passes through the second stop junction into the overflow region only after sample has filled the measurement area" (support at, for example, page 8, lines 13-19; page 13, lines 4-16 and FIGs. 7 through 7C of the disclosure). In addition, claim 1 and dependent claims 2-10 have been amended to correct informalities and to clarify the claimed subject matter.

It is respectfully submitted that the amendments above are supported by the specification, claims, abstract of the disclosure, and drawings as originally filed, and that no new matter has been added.

Objection to the Specification:

The disclosure was objected to due to the presence of informalities. Applicant submits that the disclosure, as amended, does not contain any known informalities.

35 U.S.C. §103 Rejections:

The subject matter of claims 1-5 was rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent 6,001,307 to Naka et al. (hereinafter "Naka") in view of U.S. Patent 4,426,451 to Columbus (hereinafter "Columbus").

Naka, as understood, describes a device for analyzing a sample that includes a suction pressure generating means, a drawing channel, an analytical section and a bypass channel (see, for example, col. 2, lines 48-57; col. 12, lines 65-67 and col. 13, lines 9-15 of Naka).

Columbus appears to describe a reaction vessel that includes first and second zones and a passageway between the zones that includes a meniscus control means for stopping a liquid meniscus until an externally generated pressure sufficient to push the meniscus is applied (see, for example, col. 2, lines 1-5 and 19-26 of Columbus). Columbus teaches that the passageway/meniscus control means can include angled sidewalls configured to avoid air entrapment (see, for example, page 13, lines 2-20 of Columbus).

Independent claim 1, as amended, recites the presence of first and second stop junctions wherein the second stop junction has a boundary that "forms an angle." In addition, amended claim 1 recites that:

> . . . the second stop junction is weaker than the first stop junction such that the excess sample passes through the second stop junction into the overflow region only after sample has filled the measurement area.

Neither Naka nor Columbus describe, teach or suggest the use of two stop junctions, one with an angled boundary, configured such that excess sample will flow through the second angled stop junction into an overflow region only after a measurement area has been filled. As noted in the Office Action, Naka does not describe angled stop junctions (see page 3, lines 18-19 of the present Office action). Furthermore, while Columbus describes a meniscus control means that the Office Action considers to include an angled stop junction, Columbus does not describe, teach or suggest that such an angled stop junction can be combined with another stop junction in a manner that renders the angled stop junction "weaker" in comparison to the other stop junction and that provides for an overflow region to be filled only after a measurement area is filled.

In addition, Columbus teaches that an "externally generated pressure" must be applied to overcome the meniscus control means. In contrast, the second stop junction of claim 1 is overcome once the measurement area is filled, thus requiring no pressure to be generated externally of the diagnostic medical device.

For at least the foregoing reasons, Applicant submits that independent claim 1 is novel, unobvious and, therefore, allowable over Naka and Columbus. Since claims 2-5 depend from and further limit claim 1, they are allowable for at least the same reason.

The subject matter of claims 1-10 was rejected under 35 U.S.C. §103(a) as obvions over U.S. Patent 6,261,519 to Harding et al. (hereinafter "Harding") in view of Columbus. Harding, as understood, describes a fluidic diagnostic device with a sample port, a bladder, a channel, a measurement area and a bypass channel (see, for example, col. 6, line 53 through col. 7, line 10 of Harding).

As acknowledged in the Office Action, Harding does not describe the angled stop junction subject matter of current claim 1 (see page 6, lines 1-2 of the Office Action). The deficiencies of Columbus with respect to the subject matter of amended claim 1 are discussed above. Therefore, Applicant respectfully submits that claim 1, as amended, is novel and unobvious over the combination of Harding and Columbus. For at least the foregoing reason, Applicant submits that independent claim 1 is allowable over Harding and Columbus. Since claims 2-10 depend from and further limit claim 1, they are allowable for at least the same reason.

The subject matter of claims 1-10 was rejected under 35 U.S.C. §103(a) as obvious over EP 974,840 to Shartle et al. (hereinafter "Shartle") in view of Columbus. Shartle appears to describe a fluidic medical device that includes a bladder, a measurement area and a stop junction (see, for example, col. 5, lines 38-44 of Shartle).

The Office Action states that Shartle does not describe the angled stop junction subject matter of claim 1 (see page 6, lines 17-18 of the Office Action). The deficiencies of Columbus with respect to the subject matter of amended claim 1 are discussed above. Therefore, Applicant respectfully submits that claim 1, as amended, is novel and unobvious over the combination of Shartle and Columbus. For at least the foregoing reason, Applicant submits that independent claim 1 is allowable over Shartle and Columbus. Since claims 2-10 depend from and further limit claim 1, they are allowable for at least the same reason.

CONCLUSION

Applicant respectfully requests that, in light of the amendments and explanations above, the Examiner reconsider and withdraw her rejections. Applicant respectfully submits that the claims are in condition for allowance. In the event that minor claim amendments are necessary to meet formal requirements, Applicant invites the Examiner to telephone the undersigned at (408) 956-4790 so that issuance can be expedited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version with markings to show changes made".

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

1. (Amended) A medical diagnostic device for measuring at least one of an analyte concentration [or] and a property of a biological fluid, comprising
   a. a sample inlet for introducing a sample of the biological fluid into the medical diagnostic device;
   b. a first capillary channel for conveying the sample from the sample inlet to a branching point;
   c. a capillary connecting channel for conveying a first part of the sample from the branching point through a measurement area, in which is measured a physical parameter of the sample that is related to the at least one of the analyte concentration [or] and property of the biological fluid, and, thereafter, to a first stop junction;
   d. a capillary bypass channel for conveying a second part of the sample in a first direction from a first region, proximate to the branching point, to an overflow region, distal to the branching point, the first region having a capillary dimension in a second direction substantially perpendicular to the first direction;
   e. a second stop junction in the capillary bypass channel, comprising a boundary region that
      i) separates the first region and overflow region[s],
      ii) has a second predetermined dimension in the second direction that is greater than the capillary dimension, and
      iii) forms an angle that points toward the first region, whereby [any] excess sample that enters the sample inlet will pass through the second stop junction into the overflow region;

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and wherein the second stop junction is weaker than the first stop junction such that the excess sample passes through the second stop junction into the overflow region only after sample has filled the measurement area.

1. (Amended) The medical diagnostic device of claim 1, further comprising a suction device, in fluid communication with the first and second stop junctions, for drawing the sample from the sample inlet toward the first and second stop junctions.

2. (Amended) The medical diagnostic device of claim 2, in which the medical diagnostic device further comprises a first layer and second layer, at least one of which has a resilient region over at least a part of its area, separated by an intermediate layer, and in which

a) cutouts in the layers form, with the layers, the sample inlet, firstcapillary channel, capillary connecting channel, measurement area, and capillary bypass channel;

b) the suction device comprises a bladder that

i) is distal from the sample inlet,

ii) comprises at least a part of the resilient region, and

iii) has a volume that is at least about equal to the combined volume of the first capillary channel, measurement area, capillary connecting channel, and capillary bypass channel, and

c) the first and second stop junctions comprise coinciding holes in the first, second and intermediate layers that are sandwiched by a third layer and a fourth layer.

1. (Amended) The medical diagnostic device of claim 3 in which at least one of the first [or] and second layer is substantially transparent adjoining the measurement area, and the physical parameter that is measured is optical transmission.

2. (Amended) The medical diagnostic device of claims 3 in which the physical parameter of the sample undergoes a change in the measurement area.

3. (Amended) The medical diagnostic device of claim 5 in which the measurement area contains a composition that facilitates blood clotting, the biological fluid is whole blood, and the property being measured is prothrombin time.

4. (Amended) The medical diagnostic device of claim 6 in which the composition comprises thromboplastin.

5. (Amended) The medical diagnostic device of claim 6 further comprising at least one additional fluidic path from the branching point to the bladder, each such [alternate] additional path including a corresponding measurement area and stop junction.

6. (Amended) The medical diagnostic device of claim 8 in which a first [alternate] additional path [is to a] includes corresponding measurement area that overcomes the effect of an anticoagulant and a second [alternate] additional path [is to a] includes a corresponding measurement area that partially overcomes the effect of an anticoagulant.

7. (Amended) The medical diagnostic device of claim 9 in which the corresponding measurement area [in] of the first [alternate] additional path comprises thromboplastin, bovine eluate, and recombinant Factor VIIa and the corresponding measurement area [in] of the second [alternate] additional path comprises thromboplastin and bovine eluate.